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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,588	10/23/2001	Ragab El-Rashidy	PPI-131	4852

7590

07/05/2002

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 07/05/2002 4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/044,588

Applicant(s)

EL-RASHIDY ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4 and 7-10 is/are allowed.
- 6) ☒ Claim(s) 5 and 6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 1-10 are presented for prosecution on the merits.

Claim Objections

1. Claim 5 is objected to because of the following informalities: in claim 5, line 28, "comprising" should be deleted and replaced with --comparing--. Please see the specification, page 39, lines 23-25. Appropriate correction is required.

Priority

Applicant's claim for priority to grandparent application 08/231,250 is noted. However, A claim can only have one effective filing date. Please see Studiengesellschaft Kahle m.b.H. v. Shell Oil Co., 42 USPQ2d 1674, 1677 (Fed. Cir. 1997). In the instant application the method claims 1-4 and 7-10 have support back to 08/231,250 which was filed April 22, 1994; however, claims 5-6 which set forth a specific diagnostic method involving nasal administration do not have support in the earlier filed parent applications. Therefore, claims ⁵⁻⁶~~7-10~~ of the instant application will be treated as having an effective filing date of Oct. 23, 2001.

Allowable Subject Matter

Claims 1-4 and 7-10 are free from the prior art because the prior art does not disclose or fairly suggest Applicant's claimed methods.

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Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over El-Rashidy et al., 5,770,606.

El-Rashidy et al. disclose a method of treating erectile dysfunction in a male patient comprising administering sublingually or intranasally effective amounts of apomorphine. Please see col. 7- col. 9, line 31. El-Rashidy et al. additionally disclose that sublingual administration may be used to diagnose male human patients suffering from erectile dysfunction. The diagnosing method includes the sublingual administration of apomorphine to a human male patient and exposing the patient to visual erotic stimulus. Then the maximum increase in penile circumference (tip and basal circumference) and the patient's maximum penile rigidity (tip and basal rigidity) are determined and compared to predetermined base values. Please see col. 14, lines 24-39.

El-Rashidy et al. do not specifically disclose that the diagnostic method includes nasal administration of apomorphine; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the diagnostic method of El-Rashidy et al. to include nasal administration because like sublingual administration, El-Rashidy et al. teaches that nasal administration was effective in eliciting erections (col. 9, lines 26-27), and one of ordinary skill in the art would reasonably expect the nasal dosage forms to be equally effective in diagnosing a male patient suffering from erectile dysfunction. In other words, one of ordinary skill in the art would be motivated to use nasal administration in diagnosing a male patient with the reasonable expectation that, as the nasal dosage form of apomorphine elicits an erection in

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the male patient, the maximum increase in penile circumference (tip and basal circumference) and the patient's maximum penile rigidity (tip and basal rigidity) may be determined and compared to predetermined base values.

Conclusion

Claims 5-6 are rejected.

Claims 1-4 and 7-10 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

June 29, 2002


Cybille Delacroix-Muirheid
Patent Examiner Group 1600